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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/315,688	05/20/1999	EDWARD SHANBROM	38786.00069	6828

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EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
1744	14

DATE MAILED: 04/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/315,688	SHANBROM, EDWARD	
	Examiner	Art Unit	
	Kaj Olsen	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 February 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 1 and 4 set forth a method for the determination of a “wide variety” of antioxidants. This is indefinite because it is unclear what the metes and bounds of the term “wide variety” are. What would one of ordinary skill in the art reasonably construe as being a wide variety of antioxidants?

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen and Coetzee as applied in previous office actions, and in further view of Motonaka et al (Bunseki Kagaku, 44, pp. 1013-1019 (1995)), and/or applicant’s admitted prior art. All references were previously provided. Motonaka is being utilized for the first time with this office action.
5. Chen discloses a method of determining the level of a dietary antioxidant (ascorbic acid) in a dietary material (a beverage) by exposing a liquid sample to iodine solution and measuring a change in concentration of iodide ions using a iodide-cyanide selective electrode (see translation

of Chen provided with this office action). Chen did not disclose the use of a solution of iodine with an iodophor. However, Coetzee in an alternate analytical technique discloses that iodine complexed with iodophors such as polyvinylpyrrolidone is a preferable source of iodine due to its greater stability than that of iodine solutions (see first paragraph). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize an iodophor in order to stabilize the source of iodine.

6. With respect to the new limitations drawn to the use of the method for the determination of a “wide variety” of antioxidants (see 112 rejection above), Motonaka teaches that the iodine reaction utilized by Chen and Coatzee also reacts with other dietary antioxidants such as β -carotene and vitamin A (see scheme 1) and that the measure of the liberated iodide ion can be used to determine a measure of a mixture of analytes (see (c) of fig. 2 and 3). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Motonaka for the method of Chen and Coatzee in order to extend the utility of the method to other antioxidants present in a dietary sample. The combination of ascorbic acid, β -carotene, and vitamin A would appear to read on the term “wide variety” giving the claim language its broadest reasonable interpretation. In addition, admitted prior art teach that a number of techniques that rely on the reduction of substance in the presence of an antioxidant (bromine, FRAP) find utility as measurements for the composite antioxidant levels in dietary samples (pp. 3 and 4). Because iodine has already been identified as a substance that reacts with a number of antioxidants and that the iodide liberated by the iodine reduction can be utilized to determine the levels of the substance that reduced the iodine (i.e. the antioxidants), one possessing ordinary skill in the art would be motivated in view of the prior art to utilize the

technique of Chen and Coatzee (with or without suggestion by Motonaka) for a measure of a composite antioxidant level.

7. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solinas (Ind. Agr. (Florence) (1968), 6, pp. 21-24 (CAS abstract only)) in view of Chen or Christova (Anal. Chim. Acta, 85, pp. 301-307, (1976)) and Coatzee. Solinas and Christova are being provided and utilized for the first time with this office action. Chen and Coatzee has been utilized and provided previously.

8. Solinas teaches a method for correlating the antioxidant concentration of a dietary sample (olive oil) to the measurement of the peroxide number of the fluid (see abstract). The peroxide number is determined via a iodometric method. Iodometry is a process where iodine is titrated with the analyte and produces iodide ions. Hence, iodometry derives the measurement of the reduceable analyte (in the case of Solinas, peroxides) from the amount of iodine consumed in the reaction. This would not constitute a measurement of the change in the concentration of iodide ions as required by the claims. However, both Chen and Christova teach that the amount of reductants reacted with iodine can also be monitored by measuring the iodide concentration (see rejection with Chen above and see abstract of Christova). Measuring the iodide concentration itself provides a direct measure of the amount of analyte (as opposed to titrations) and provides reductant detection limits that are superior to almost all other known means for measuring means (see Christova, "Discussion", first paragraph). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teachings of either Chen and/or Christova for the method of Solinas in order to arrive at a direct measurement of the reductants (such as peroxides) with superior detection limits.

9. With respect to the use of an iodophor, Coetzee in an alternate analytical technique discloses that iodine complexed with iodophors such as polyvinylpyrrolidone is a preferable source of iodine due to its greater stability than that of iodine solutions (see first paragraph). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize an iodophor in order to stabilize the source of iodine.

Response to Arguments

10. Applicant's arguments concerning the absence of the teaching of Chen of measuring a "wide variety" of antioxidants is moot in view of the new grounds of rejection presented above. However, applicant's arguments concerning whether the method of Chen fails to measure the carotenoids or phenolics in mango juice will be briefly addressed. In particular, applicant suggests that the method of Chen failed to measure the presence of phenolics and carotenoids because both should be present in mango juice (as opposed to the "fresh orange crystals" which the applicant is presuming has ascorbic acid as the sole antioxidant) and there is no indication by Chen of any discrepancy in their measurement. However, given the similarity of the method of the instant invention to the method set forth by Chen, this argument as currently being presented in applicant's remarks does not rise to the level of *prima facie* evidence of the failure of the method of Chen to react with phenolics and carotenoids. Both the instant invention and Chen rely on the reduction of iodine with the antioxidant, and iodine has a fundamental redox potential that would seem determine whether it reacts with the antioxidant or not. Applicant suggests the use of the buffer by Chen or the elevated temperatures of Chen might be responsible. Either possibility is unpersuasive absent further elucidation in an appropriate Declaration by the

applicant. The examiner is not aware of any evidence that carotenoids or phenolics would break down in a conventional solvent in temperatures that are not much higher than the temperature of human body (antioxidants presumably survive conventional cooking temperatures that are much higher than the temperatures utilized by Chen). With respect to the use of an iodophor, the use of an iodophor was rendered obvious by the teaching of Coetzee and applicant's have not suggested any unexpected results from the use of an iodophor versus straight iodine. In addition, Motonaka already teaches that iodine reacts with the carotenoid β -carotene without the presence of the iodophor (see rejection above). Finally, the applicant presumes that Chen verified his result with an independent measurement. The examiner finds no basis for said presumption. Even if Chen did verify their results, it is unclear if the independent means utilized can also differentiate between ascorbic acid and other antioxidants because a number of techniques in the art don't appear to differentiate different antioxidants from each other (see instant invention's discussion of the prior art).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kohen (USP 6,108,570) is an alternate antioxidant measuring means, but is not drawn to dietary antioxidants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 8:30 AM-6:00 PM. The examiner can also be reached on alternate Fridays.

Art Unit: 1744

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for non-after final communications is (703) 872-9310 and the fax number for after-final communications is (703) 872-9311.

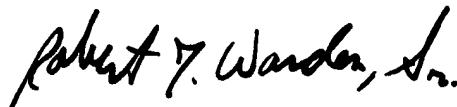
Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

Kaj K. Olsen, Ph.D.



Patent Examiner

AU 1744



ROBERT J. WARDEN, SR.
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